



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

January 27, 2005

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

Ref. KAN 2005-06

William H. Newhouse, President
Newhouse Dairy Processing LLC
4370 Vermont Terrace
Wellsville, KS 66092-8837

Dear Mr. Newhouse:

The U.S. Food and Drug Administration (FDA) inspected your firm, located at 4370 Vermont Terrace, Wellsville, KS 66092, on July 23rd and 29th, as well as on August 13, 2004, and found that you have serious deviations from the Juice HACCP regulation (21 CFR Part 120). These deviations cause your fresh squeezed orange juice to be in violation of section 402 (a)(4) of the Federal Food, Drug, and Cosmetic Act (Act). You can find this Act and the juice HACCP regulation through links in FDA's home page at www.fda.gov.

The deviations were as follows:

- You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 120.6(c). However, your firm did not maintain sanitation control records for the safety of water; the condition and cleanliness of food contact surfaces; the prevention of cross contamination from insanitary objects to food, food packaging material, and other food contact surfaces, and from raw product to processed product; the maintenance of hand washing, hand sanitizing, and toilet facilities; the protection of food, food packaging materials, and food contact surfaces from adulteration with chemical physical and biological contaminants; proper labeling, storage, and use of toxic compounds; control of employee health conditions; and, exclusion of pests.
- You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 120.8(b)(1). However, your firm's HACCP plan for fresh squeezed orange juice does not list the food safety hazard of pathogens, for example.
- You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 120.8(b)(3). However, your firm's HACCP plan for fresh squeezed

orange juice does not list a critical limit at critical control point 3, "Sanitize", to control sanitizer concentration and contact time.

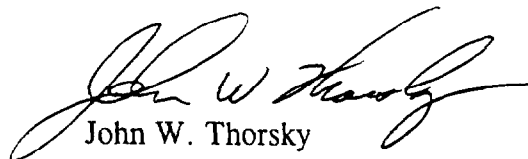
- You must perform end-product testing, in accordance with 21 CFR 120.25, of citrus juice that rely in whole or in part on surface treatment, to comply with 21 CFR 120.11(a)(1)(vi). However, your firm did not conduct end-product testing for your fresh squeezed orange juice.
- You must have a HACCP plan that list monitoring procedures for each critical control point, to comply with 21 CFR 120.8(b)(4). However, your firm's HACCP plan for fresh squeezed orange juice lists a monitoring procedure of "Note any large amount of culling" at the "Primary Cull" critical control point that is not adequate to control pathogens. This procedure does not ensure conformance with the critical limit of "#1 fruit only."

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

In either case, it is essential that you respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct the deviations. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

Please send your reply to the U.S. Food and Drug Administration, Attention: Joseph G. Kramer, Compliance Officer, at the address noted in the letterhead. If you have any questions regarding any issue in this letter, please contact Mr. Kramer at (913) 752-2719.

Sincerely,



John W. Thorsky
Acting District Director
Kansas City District